REMARKS

Favorable reconsideration is respectfully requested in view of the above amendments and following remarks. Claim 1 has been amended. The amendment to claim 1 is supported by previous claim 28. Claim 28 has been canceled without prejudice or disclaimer. No new matter has been added. Claims 1, 4-5, 11-27 and 30-32 are pending.

Claim rejections - 35 U.S.C. § 103

Claims 1, 4-5, 11-15, 25-26, 28 and 30-32 are rejected as being unpatentable over WO 02/078568 A1 (Browning) in view of US Patent No. 5,447,940 (Harvey et al.). Applicants respectfully traverse the rejection.

The rejection contends that it would have been obvious to combine Browning and Harvey and fully integrate the knit layer as suggested by Harvery into the absorbable coating of Browning. Even accepting, arguendo, the rejection's position that Harvey teaches a configuration where the reinforcing material and the gelatin film are integrated due to gelation of gelatin that has intruded entirely in an internal part of the reinforcing material, the rejection's analysis of the combination of the references is incorrect.

In particular, Harvey is directed to absorbable composite materials that are specifically adapted for the treatment of periodontal disease (col. 1, lines 6-8). Harvey is focused on the non-surgical approach for the treatment of periodontal disease where medicated films are inserted into the periodontal pocket followed by slow release of a chemotherapeutic agent over a period of time (col. 2, line 57 to col. 3, line 36). Harvey indicates that there are four requirements for such medical films: (1) the film should be stiff when dry so that it is easy to insert deep into the periodontal pocket; (2) the film should be soft and comfortable once inserted into the pocket; (3) the film should be retained in the periodontal pocket for extended periods without falling out; and (4) the film should release the active agent at a controlled rate (col. 2, lines 1-19). To address these issues, Harvey provides a composite material including a collagen matrix reinforced with a layer of a bioabsorbable polymer and having an active agent dispersed therein (col. 2, lines 37-42). Harvey indicates that their composites are rigid when applying the composite material, and become soft when they absorb fluid at the application site (col. 6, lines 62-67). Harvey teaches that the steps for producing their composites include pouring homogenized collagen slurry over the reinforcing layer and air or freeze drying (col. 5, lines 1-6).

Harvey further indicates that their composites swell so that they are held firmly in place without the need for any additional retaining means, for up to 30 days (col. 6, line 67 to col. 7, line 2).

It can be clearly understood by the above description that integration of the gelatin is intended to provide rigidity to the composite before application so that the composite may be inserted into a deep periodontal pocket, that surgical procedures are not involved in the use of the composite, and that the composite is intended to be removed after 30 days.

Browning is focused on an implant used during surgical treatment that includes a mesh and a coating for the surgical treatment of sensitive tissues, such as vaginal tissue. Browning notes that conventional meshes are generally unnecessarily strong for use in the treatment of sensitive tissues, and distinguishes their mesh from the prior art by noting that their mesh is configured to provide only a sufficient tensile strength to securely support the defect and tissue being repaired so as to avoid the mesh being felt when placed into position (page 5, lines 27-29 and page 7, lines 27-29). Browning further teaches that their surgical implant is comprised of narrow members arranged to be spaced by relatively wide gaps and major spaces, and notes that it is desirable for the mesh to have means for promoting tissue in-growth between the members (page 9, line 29 to page 10, line 1). Browning also teaches that two filaments can be interwoven/knitted to produce strands of the mesh comprising pores, and it is desirable to provide pores in the strands of the mesh to further aid tissue in-growth between the members (page 10, lines 1-4). The reference indicates that this is important in enabling efficient fibroblast throughgrowth and ordered collagen laydown in order to provide optimal integration into the body (page 10, lines 27-31). Browning indicates that a mesh having such narrow members or strands that are widely spaced will inevitably be somewhat flimsy and lacking in rigidity compared to conventional meshes, and addresses this issue by providing a configuration where the absorbable coating is provided on one or both of the outer surfaces of the mesh (page 12, lines 7-14; page 38, lines 8-14 and page 38, line 27 to page 39, line 2).

It is clear from the above discussion that Browning is focused on an implant used during surgical treatment, as opposed to non-surgical treatment, that their implant is configured for sensitive tissue such as vaginal tissue that requires a flexible material, as opposed to a rigid material, during application, that their implant is configured for full integration, as opposed to temporary placement, into the body by providing hollow spaces between or within the members so as to aid tissue in-growth between the members, that this feature is particularly important to

provide efficient cell throughgrowth and collagen laydown, and that their implant is configured such that the absorbable coating is provided on one or both of the outer surfaces of the mesh, as opposed to the gelatin infiltrating the mesh.

The rejection contends that it would have been obvious to fully integrate the knit layer as suggested by Harvey et al. into the absorbable coating of Browning motivated by the desire to create an absorbable composite that is easy to handle, can be cut into any desired shape, soft and comfortable, while maintaining good structural integrity. However, the references teach entirely different configurations to address entirely different needs.

In particular, Browning is directed to an implant that is intended to be used in surgical applications, while Harvey is directed specifically to composite material for non-surgical treatments. Browning's implant also is configured for sensitive tissues, such as vaginal tissue, where the use of Harvey's rigid composite material would be inappropriate for such applications. In fact, Browning clearly suggests that the use of any rigid material that can be felt by the patient when in position would be undesirable (page 5, line 27 to page 6, line 6).

Moreover, Harvey's composite is configured for temporary placement in the periodontal pocket for drug release such that the composite is not integrated with the body, and places particular importance to providing a rigid structure to the composite before application by integrating the gel into the mesh. On the other hand, Browning's implant is particularly configured for full integration into the body, and teaches that the desired optimal integration is achieved by providing hollow spaces between or within the members so as to aid tissue in-growth between the members. As such, it can be clearly understood that Browning in fact leads away from the configuration of Harvey's rigid composite material where the gel is fully or partially integrated into the mesh. Accordingly, claim 1 and the dependent claims therefrom are patentable over the references taken alone or separately for at least the above reasons.

Even further, claim 1 requires a yarn of the warp knitted fabric to include a multifilament yarn, the thickness of the yarn to be in a range of 30 to 200 d (33.3 decitex to 222.2 decitex), and the medical film to serve as an antiadhesive material.

Advantageously, the properties of the medical film required by claim 1 are such that the film is biocompatible and still can perform an antiadhesive function. In particular, by having a yarn of the warp knitted fabric that includes a multifilament yarn, and the thickness of the yarn to be in a range of 30 to 200 d (33.3 decitex to 222.2 decitex) as required by claim 1, the gelatin

film can infiltrate into areas between filaments so that the reinforcing material and the gelatin film can become integrated with each other (see, e.g., page 39, lines 7-25 of the specification). These features required by claim 1 allow the medical film to perform its function by providing durability and strength to the medical film, e.g., allowing suturing to be carried out as many times as needed to ensure that the medical film is secured at the application site (page 3, lines 23-27 of the specification). In addition, by having a reinforcing material that is made of a biodegradable polymer as required by claim 1, the medical film can be degraded after performing its function and then can be absorbed in the living body so that a foreign body reaction with tissues therein can be avoided (page 3, line 28 to page 4, line 1).

In contrast, Browning's mesh is configured to achieve a result that is opposite to that of claim 1. That is, as noted above, Browning's surgical implant includes a mesh with a diminished strength and increased flexibility as compared to conventional meshes so that the use of sutures is negated (page 11, line 13 to page 12, line 5). As such, contrary to the rejection's position, nothing in Browning provides any reasonable basis for using a yarn that includes a multifilament yarn having a thickness in a range of 30 to 200 d so that the medical film can serve as an antiadhesive material as required by claim 1. As indicated above, Browning leads away from the teachings of Harvey. Accordingly, claim 1 and the dependent claims therefrom are further removed from Browning and Harvey for these reasons.

Claim 16 is rejected as being unpatentable over WO 02/078568 A1 (Browning) in view of US 5,447,940 (Harvey et al.) as applied above, and further in view of U.S. Patent No. 5,854,381 (Jurgens). Applicants respectfully traverse the rejection.

Claim 1 has been distinguished above. Jurgens does not remedy the deficiencies of Browning and Harvey. Claim 16 depends from claim 1, and is patentable over the references for at least the same reasons discussed above for claim 1. Applicants do not concede the correctness of the rejection.

Claims 17-24 are rejected as being unpatentable over WO 02/078568 A1 (Browning) in view of US 5,447,940 (Harvey et al.) as applied above, and further in view of EP 1022031 (Matsuda). Applicants respectfully traverse the rejection.

Claim 1 has been distinguished above. Matsuda does not remedy the deficiencies of Browning and Harvey. Claims 17-24 depend from claim 1, and are patentable over the

references for at least the same reasons discussed above for claim 1. Applicants do not concede the correctness of the rejection.

Claim 27 is rejected as being unaptentable over WO 02/078568 A1 (Browning) in view of US 5,447,940 (Harvey et al.) as applied above, and further in view of U.S. Patent No. 4,374,063 (Consolazio et al.). Applicants respectfully traverse the rejection.

Claim 1 has been distinguished above. Consolazio does not remedy the deficiencies of Browning and Harvey. Claim 27 depends from claim 1, and is patentable over the references for at least the same reasons discussed above for claim 1. Applicants do not concede the correctness of the rejection.

In view of the above, favorable reconsideration in the form of a notice of allowance is requested. Any questions or concerns regarding this communication can be directed to the attorney-of-record, Douglas P. Mueller, Reg. No. 30,300, at (612) 455.3804.

Respectfully submitted,

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